

Animalgesic Labs

Animalgesics® for Mice & Rats (extended-release buprenorphine)

Animalgesics is now authorized by the FDA to be legally marketed for safe and effective control of post-procedural pain in rats. One *injection provides clinically significant analgesia in mice and rats for 2-3 days*

- *Meet Animal Care and Use Committee compliance requirements for pain management in mice and rats with a pharmaceutical quality extended-release buprenorphine*

Baltimore, MD – Animalgesics Labs Inc. announced today that the FDA has authorized the addition of the species rat to the label of the existing *Animalgesics for Mice*. *Animalgesics for Mice & Rats* is an FDA indexed, extended-release formulation of buprenorphine HCl, or **buprenorphine sustained release** that provides 2-3 days of clinically significant analgesia in mice and rats with a single injection.

Animalgesics for Mice & Rats, or **buprenorphine extended release**, is scheduled to be available for shipment in the second half of September 2014, and can be ordered either direct through Animalgesic Labs or from Henry Schein Animal Health.



An independent Expert Panel approved by the FDA to review Target Animal Safety and Efficacy Studies concluded "*Animalgesics for Mice & Rats* is both safe and efficacious for relief of post-procedural pain in rats when used under the conditions described on the proposed product label. The effective period for **buprenorphine for mice**, under

label use conditions and from the available data, appears to be 2-3 days."

"There are innumerable confounding factors that need to be controlled during

well-executed experiments. Pain is a major confounder that affects almost all organ systems and homeostatic processes. At last, there is a safe and effective option for pain control in rodents that does not increase stress due to multiple injections," states Dr. Elizabeth Johnson, CEO Veterinary Bioscience Institute.

More on *Animalgesics for Mice & Rats*

Animalgesics for Mice & Rats is available in the US and packaged for use in the form of an injectable suspension. **Extended release buprenorphine** comes in 3.0 ml vials of 30 doses for the average 200 g rat. The product is available in the United States. One injection given at time of procedure provides 2-3 days of clinically significant **buprenorphine rats** analgesia. Buprenorphine HCl, an opioid analgesic, is the active ingredient in *Animalgesics for Mice & Rats* and is lipid-bound and suspended in medium chain fatty acid triglyceride (MCT) oil. Lipids encapsulate the buprenorphine limiting diffusion, which provides for larger doses and prolonged action. *Animalgesics for Mice & Rats* is manufactured under strict manufacturing conditions of the FDA's Current Good Manufacturing Practices (CGMPs) for human and veterinary pharmaceuticals.

More Information on FDA Indexing

For a veterinary product to be legally marketed it must be Approved, Conditionally Approved, or Indexed by the FDA's Center for Veterinary Medicine. *Animalgesics for Mice & Rats* is Indexed. For **buprenorphine mice** product label information on the FDA website visit:

<http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/UCM373294.pdf>

About Animalgesic Labs

Animalgesic Labs is a specialty pharmaceutical company specializing in the development and commercialization of products for pain management in rodents. We are committed to the welfare of research animals and have focused our resources on being the industry leader in developing quality analgesic products for rodents, such as **sustained release buprenorphine**, as we know enhancing animal welfare improves research and benefits the advances in biomedical research.

Corporate offices are located in Baltimore, MD. For more details please visit our website: <http://www.animalgesiclabs.com>

[Contact Name for Reporters]

Title: Kelly Barton, RLATG - Product Applications Director

Phone: 410.846.0042

Email: kbarton@animalgesiclabs.com